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10 November 1999

CRITICARE SYSTEMS, INC.

510K Summary

MPT 24 and VitalView 24
w/ Event Based Paging

Contact: Alex Kaplan
Director QA & RA
Criticare Systems, Inc.
20925 Crossroads Circle
Waukesha, WI 53186 USA
262-798-8282

Trade Name: MPT 24 and VitalView 24

Common Name: Ambulatory Telemetry System

Classification Name: System, Telemetry, Physiological Signal ~~(84GYE)~~ DRG/74

Substantial Equivalence is claimed to : CSI Multiple Parameter Telemetry (MPT) / Vital View (VV) System (K961223)

Device Description:

The MPT™ 24 (Multi Parameter Telemetry 24) is a battery powered patient borne ambulatory telemetry monitor utilizing bi-directional 2.4GHz RF communications to and from the VitalView 24 (VV 24) central station. The MPT 24 is capable of simultaneously monitoring ECG, pulse oximetry, and non-invasive blood pressure. An LCD display is incorporated for the real-time review of patient ECG and S_pO_2 waveform and numerical patient data while connected to the monitored patient.

A typical system consists of up to eight MPT 24 monitors per Vital View 24 central station wirelessly communicating via a network of access points and their associated antennas. The Vital View central also has embedded capability to send messaging text and patient alarms to a caregiver worn pager, the RemoteView™ pager. All RF communications with monitors and pagers are limited to a typical distance of 75 ft from the nearest RF antenna node.

Intended Use:

The VV 24 and MPT 24 monitoring system is intended to be used in any healthcare environment where any combination of ECG, S_pO_2, and NIBP parameters are required to assist in patient care surveillance. The VV 24 system's paging capability acts as a secondary notification of patient alarms.

Comparison with predicate device:

Patient telemetry monitoring has been utilized for over two decades worldwide. Typical RF communications in the past and present has utilized the VHF and UHF spectrum. Typical telemetry monitoring has progressed from single ECG lead monitoring through multiple ECG lead monitoring to simultaneous multiple parameter monitoring with multi-lead ECG and additional physiological parameters. The latter is exemplified by the market introduction of the MPT™ system from Criticare Systems, Inc in 1996 followed by Hewlett-Packard's Viridia™ Telemetry and GE Marquette's PRISM™ Telemetry. Criticare Systems, Inc newest system utilizes the 2.4 GHz RF spectrum for it's monitoring systems wireless communications applications which affords a more reliable telemetry signal that is less likely to be affected by surrounding RF interference compared to standard VHF or UHF spectrum use. The actual monitoring capability of the MPT 24 system is it's unique ability to monitor ECG, NIBP, and S_pO_2 from a singular battery operated device with an LCD display. The paging capability of the VV 24 system is different only in that it is embedded in the system rather than dependent on ancillary paging systems.

Clinical testing:

Testing was accomplished at two customer sites. Site One was located within the United States and Site Two was located internationally to get a cross section of evaluation from two similar yet distinctive user cultures. The purpose of this beta testing was to install the system in a controlled real life environment with Criticare clinical and technical personnel present at the facility during the beta period.

The domestic evaluation was to be performed by a minimum of 10 users. The patient on time was expected to be variable therefore the number of patients being monitored does not enter into the evaluation of the system.

The international evaluation, because of patient population constraints, was structured as follows:

- VitalView24 and MPT24 ECG Validation sheet – minimum of 5 patients
- VitalView24 and MPT24 Pulse Oximetry Validation sheet – minimum of 5 patients
- VitalView24 and MPT24 Non Invasive Blood Pressure (NIBP) Validation sheet – minimum of 5 patients
- VitalView24 and MPT24 New Feature Validation sheet – minimum of 3 hospital staff personnel

The domestic beta evaluation showed a 92.4% Excellent or Very Good rating of system features and 76.7% Excellent or Very Good rating for the overall system.

The international beta evaluation led to improved installation procedures and resolution of discovered software idiosyncrasies.

Both beta evaluations demonstrated that the system is a safe and effective product for its intended use with a high overall acceptance rating.

Compliance to standards and regulations:

The MPT 24 and VitalView 24 system complies with the following national and international standards:

CSI Cat 507VVS Central Station CPU and Display
IEC 950 Electrical Safety
EN1060-1 NIBP Performance
EN 1060-3 NIBP Performance {including EN 475 Alarm Performance}
IEC 601-2-27 ECG Safety
AAMI EC-13 ECG Performance
EN 865 Oximetry Performance {including EN 475 Alarm Performance}
IEC 601-1-2 EMC Compliance
ETS 300 826 EMC Compliance for Intentional Radiators
Country Type Approvals for Intentional Radiators

CSI Cat 507MPS Patient-Borne Telemetry Monitor
EN 60601-1 Medical Electrical Safety
EN1060-1 NIBP Performance
EN 1060-3 NIBP Performance
AAMI SP-10 NIBP Performance
IEC 601-2-27 ECG Safety
AAMI EC-13 ECG Performance
EN 865 Oximetry Performance
ISO 10993-5,10-11 Biocompatibility
IEC 601-1-2 EMC Compliance
ETS 300 826 EMC Compliance for Intentional Radiators
Country Type Approvals for Intentional Radiators

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Alex Kaplan
Director, Quality Assurance and Regulatory Affairs
Criticare Systems, Inc.
20925 Crossroads Circle
Waukesha, Wisconsin 53186

Re: K000276
Trade Name: MPT 24 and Vital View 24
Regulatory Class: II
Product Code: DRG
Dated: January 26, 2000
Received: January 31, 2000

Dear Mr. Kaplan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN) : K000276

DEVICE NAME : MULTIPLE PARAMETER TELEMETRY (MPT)/ VITAL VIEW (VV) SYSTEM

INDICATIONS FOR USE:

This system is intended to monitor the ECG, SpO_2 and NIBP of stationary and ambulatory patients inside of the hospital. The user of the monitored data displayed at a central location will be a professional health care provider. Physiological data, system alarms and patient data analysis will be available to the care provider at the central display location.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURANCE of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000276